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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,895

02/16/2006

Robert L Garcea

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EXAMINER

SALIMI, ALI REZA

ART UNIT

PAPER NUMBER

1648

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01/06/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/541,895	<b>Applicant(s)</b> GARCEA ET AL.	
	<b>Examiner</b> A R. Salimi	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,5,7-18,22-25,27,31-33,35,37 and 43-54 is/are pending in the application.
- 4a) Of the above claim(s) 1,5,7-18,22-25,27,31-33,35 and 46-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37, 43-45 and 49-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Response to Amendment***

This is a response to the amendment filed 12/05/2008. Claims 1, 5, 7-18, 22-25, 27, 31-33, 35, 37, 43-45, 46-48, and 49-54 are pending. Claims 1, 5, 7-18, 22-25, 27, 31-33, 35, 46-48 are withdrawn for reasons of record. Claims 37, 43-45 and 49-54 are under active consideration.

**Applicants are again reminded to cancel the claims to the non elected Group(s).**

Please note any ground of rejection that has not been repeated is removed.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 102***

Claims 37, 43-45 and 49-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Gissmann et al (US Patent no. 7,371,391 B2) for reasons of record advanced in the previous Office Action mailed 06/06/2008. Applicants assert Gissmann fails to recite the phrase "a second polypeptide comprising at least one immunogenic epitope" elements of independent claim 37.

Applicant's argument as part of amendment filed 12/05/08 has been considered fully, but they are not persuasive.

Gissmann et al taught chimeric protein comprising papillomavirus L1 protein and another protein wherein the composition forms capsomere. Applicants' assertions are legally erroneous (emphasis added). Applicants have engaged in words play rather than objectively evaluating the

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evidence cited by the Office. First, Applicants' understanding of adjacent protein is misplaced. The second or adjacent protein could and actually is another protein with at least one immunogenic epitope as disclosed in other dependent claims. Second, the limitation does nothing to distinguish itself from the chimeric protein taught previously. Applicants' failure to objectively evaluate Gissmann's patent does not take away from the legal and scientific bases of previously stated rejection. The facts remain that the Public prior to now claimed invention was in possession of the same invention. And the Public should not be burdened with providing yet another monopoly. Additionally, under inherency doctrine where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of anticipation has been established. See, In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). The rejection is respectfully maintained.

Claims 37, 43, 50, 52-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilson et al (US Patent no. 6,908,613 B2) for reasons of record advanced in the previous Office Action mailed 06/06/2008. Applicants assert Wilson et al fails to disclose "a second polypeptide comprising at least on immunogenic epitope" elements of independent claim 37.

Applicant's argument as part of amendment filed 12/05/08 has been considered fully, but they are not persuasive.

Wilson et al taught chimeric protein comprising papillomavirus L1 protein and another protein. Applicants' assertions are legally erroneous (emphasis added). Applicants have engaged in words play rather than objectively evaluating the evidence cited by the Office. Just

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because the same very words are not present does not mean the product does not have the same function. The facts remain that the Public prior to now claimed invention was in possession of the same invention. And the Public should not be burdened with providing yet another monopoly. Additionally, under inherency doctrine where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of anticipation has been established. See, In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). The rejection is respectfully maintained.

Claims 37, 43-45 and 49-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Hallek et al (US Patent no. 7,182,947 B2) for reasons of record advanced in the previous Office Action mailed 06/06/2008. Applicants assert Hallek fails to disclose "a second polypeptide comprising at least one immunogenic epitope" elements of independent claim 37.

Applicant's argument as part of amendment filed 12/05/08 has been considered fully, but they are not persuasive.

Hallek et al taught chimeric protein comprising papillomavirus L1 protein and another protein wherein the composition forms capsomere. Applicants' assertions are legally erroneous (emphasis added). Applicants have engaged in words play rather than objectively evaluating the evidence cited by the Office. First, Applicants' understanding of another protein is misplaced. The second or another protein could be another protein with at least one immunogenic epitope as disclosed in other dependent claims. Second, the limitation does nothing to distinguish itself from the chimeric protein taught previously. Applicants' failure to objectively evaluate Hallek's

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patent does not take away from the legal and scientific bases of previously stated rejection. The facts remain that the Public prior to now claimed invention was in possession of the same invention. And the Public should not be burdened with providing yet another monopoly.

Additionally, under inherency doctrine where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of anticipation has been established. See, In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). The rejection is respectfully maintained.

### ***Claim Rejections - 35 USC § 102***

Claims 37, 43-45 and 49-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Gissmann et al (US Patent no. 6,228,368 B1) for reasons of record advanced in the previous Office Action mailed 06/06/2008. Applicants assert Gissmann fails to disclose "a second polypeptide comprising at least on immunogenic epitope" elements of independent claim 37.

Applicant's argument as part of amendment filed 12/05/08 has been considered fully, but they are not persuasive.

Gissmann et al taught chimeric protein comprising papillomavirus L1 protein and another protein wherein the composition forms capsomere (see the abstract, and claims 1-14).

Additionally, under inherency doctrine where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of anticipation has been established. See, In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Applicants' assertions are legally erroneous. Moreover, the ration of 1 to 5 has no patentable weight. There is nothing in the

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record to show the product disclosed by Gissmann is any different than the product now claimed. The facts remain that the Public prior to now claimed invention was in possession of the same invention. And the Public should not be burdened with providing yet another monopoly. The rejection is respectfully maintained.

Claims 37, 43-45 and 49-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Garcea et al (US Patent no. 6,165,471 A) for reasons of record advanced in the previous Office Action mailed 06/06/2008. Applicants assert Garcea fails to disclose "a second polypeptide comprising at least on immunogenic epitope" elements of independent claim 37.

Applicant's argument as part of amendment filed 12/05/08 has been considered fully, but they are not persuasive.

Garcea et al taught chimeric protein comprising papillomavirus L1 protein and another protein wherein the composition forms capsomere (see the abstract, all the claims, specifically claims 1-19). There is nothing in the record to show the product disclosed by Garcea is any different than the product now claimed. Moreover, the ratio of 1 to 5 has no patentable weight. The facts remain that the Public prior to now claimed invention was in possession of the same invention. And the Public should not be burdened with providing yet another monopoly for something it already possesses. The rejection is respectfully maintained.

No claims are allowed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR



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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/A R Salimi/

Primary Examiner, Art Unit 1648

01/05/2008